

Catt et al. discloses and describes an assay device and an assay result reader combination. A preferred feature of the combination is the provision of interlocking means on a receiving means of the assay result reader, which engages with corresponding interlocking means on the assay device, "to ensure that upon receipt of said device by said reader" (a detection zone) is "located and maintained in predetermined spacial relationship relative to said reading means" (page 5, first full paragraph).

In addition, as a separate preferred feature, the "receiving means includes actuating means causing and reading" (of detection zone) "to be initiated" (page 5, second full paragraph).

These two separate features are incorporated in the embodiment depicted in Figures 4b and 5-6. This device was actually produced as a prototype by the current Applicant, but it was found to be associated with a number of problems. In particular, it was found that it was possible for an assay device to be inserted into the slot of the assay reader so as to appear superficially to be correctly positioned, but in fact to be inappropriately placed, such that the detection zone was not suitably located to provide a proper reading. One particular example of this problem is where the assay device is inserted into the slot, tip pointing downwards, so as to depress the actuator (504 in Figure 5) before the interlock (506) has engaged the co-operating recess (709, Figure 7) provided on the assay device. (Such a situation is similar to that illustrated in Figure 8 of the present application. In these circumstances the actuator 504 becomes actuated prematurely, and an erroneous assay result is obtained. There is no "lock and key" engagement between the actuating means and the assay device *per se*, merely a close fit between the assay device and the assay result reader in general.

The present invention overcomes these problems by providing an assay result reader/assay device combination in which, *inter alia*, reading of the assay result can take

place only when the assay device has been correctly positioned within the assay result reader. The solution of the present invention is to provide a lock and key engagement specifically between the actuating means and a portion of the assay device. This is not taught or suggested in Catt et al.

Adopting the "problem and solution" approach to the question of inventive step, we would submit that the problem addressed by the present claims is a problem which is not solved by the teaching of the closest prior art document, Catt et al. (as is evident from the foregoing argument). The solution to the problem not solved by Catt et al. is to ensure that the actuating means can only be actuated by the insertion of the assay device exactly in the intended 3-dimensional orientation and, in particular, by forming the actuating means with an integral 3d "interlock" feature. This solution is not proposed by Catt et al., nor is there any suggestion of such a solution to the problem, since the problem of premature actuation was not one which was anticipated by the authors of Catt et al. Indeed, had Catt et al. addressed the problem, which is solved by the present invention the Catt et al. device would have progressed beyond the prototype stage and the state of the art would not be in need of the innovative approach provided by the present invention.

Accordingly the Applicants submit the claims as earlier amended and entered by the Examiner are both novel and non-obvious over Catt et al. Withdrawal of the rejection is respectfully requested.

Claims 1 and 5-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jina et al. (U.S. 5,526,120). The Applicants respectfully traverse the rejection.

The disclosure of Jina et al. is clearly limited to an electrical connection to effect actuation. The cited reference is completely devoid of any teaching or suggestion of a "switch actuating means which is displaceable only upon correct receipt of said assay

device" (emphasis added), as required by the present invention. There is no suggestion in the reference whatsoever to modify the teaching of Jena et al to require any displacement to effect actuation. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure" *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) See MPEP 2142.

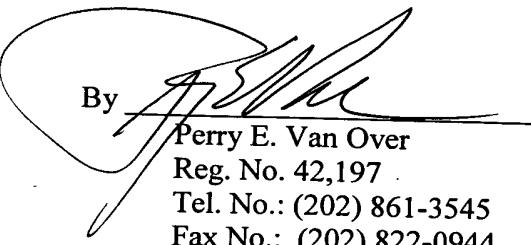
Clearly Jena et al. does not teach or suggest a modification of an electrical connection actuating switch to arrive at a "displaceable" actuating means. Accordingly, withdrawal of the rejection is respectfully requested.

All objections and rejections having been addressed, it is respectfully submitted that the present application is in condition for allowance and a Notice to that effect is earnestly solicited. If the Examiner has any questions regarding the above submitted remarks, please contact the undersigned at the telephone number provided for further discussion regarding this matter.

Respectfully submitted,

PILLSBURY WINTHROP LLP

By



Perry E. Van Over
Reg. No. 42,197
Tel. No.: (202) 861-3545
Fax No.: (202) 822-0944

PEV/pdn
1100 New York Avenue, N.W.
9th Floor, East Tower
Washington, D.C. 20005-3918
Phone: (202) 861-3000